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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,032	08/28/2003	Purnendu K. Dasgupta	067407-5116US	1527
67374 MODGAN LE	7590 05/02/2007	EXAMINER		
MORGAN, LEWIS & BOCKIUS, LLP ONE MARKET SPEAR STREET TOWER			TURK, NEIL N	
SAN FRANCISCO, CA 94105			ART UNIT	PAPER NUMBER
		•	1743	
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			05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/653,032	DASGUPTA ET AL.				
Office Action Summary	Examiner .	Art Unit				
	Neil Turk	1743				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	I. ely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status		·				
1) Responsive to communication(s) filed on						
	action is non-final.					
, <u> </u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
·	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims		·				
4) Claim(s) 1-28 is/are pending in the application.	4) Claim(s) 1-28 is/are pending in the application.					
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.		•				
6)⊠ Claim(s) <u>1-28</u> is/are rejected.	☑ Claim(s) 1-28 is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.	•				
Application Papers		,				
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>14 April 2004</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
	1: Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
	•					
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application						
Paper No(s)/Mail Date <u>4/12/04</u> . 6) Other:						

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### **DETAILED ACTION**

# Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the structural features of the claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Figures 1-1c and 9a, which appear to be drawings to the apparatus, lack clarity from their lack of relevant structural description in the specification (i.e. Examples 1 and 7) that would correlate to the claims. The drawings appear to show some sort of flow cell with inlets and outlets, but absent a proper description in the specification it is unclear how the drawings relate to the claimed elements. It further not seen anywhere in the drawings elements which would coincide with sources for the two streams.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's language in defining the apparatus, namely the flow channels and streams, is unclear. It is unclear what constitutes a "liquid sample stream wall" and a "carrier liquid stream wall"? Does Applicant intend to recite structure to the flow-through treatment channel which would provide that only the respective streams touches its respective wall by this limitation? If so, Applicant must establish structural elements and relationships within the flow-through treatment channel for such flow and contact of the two streams. Applicant has not established a liquid sample and a carrier sample in the claims. Applicant's method claims (12-28) are more illustrative to the apparatus that is shown and described in the drawings and specification.

The preamble of independent claim 1 recites that the liquid sample stream includes several elements, however these elements are not recited in conjunction with a

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liquid sample stream in the body of the claim. These limitations will not be given patentable weight where only present in the preamble of the claim.

Applicant also uses terminology such as "generally parallel" and "substantially parallel". What do these two terms mean? What is the difference between generally parallel and substantially parallel? If that the walls are opposed from each other in a generally parallel fashion how do the streams flow in a substantially parallel fashion? Further, Applicant later states that a liquid interface is formed between "said parallel streams". Is the housing and opposed walls formed in a fashion for parallel flow or is it formed in a fashion for non-parallel flow? Applicant should be clear and consistent in their recitation.

Applicant states that the matrix ion species is present a substantially lower concentration in the sample stream at the channel outlet than at the treatment inlet. It is unclear how such a relationship exists such that Applicant has not established a matrix ion species with the sample stream and furthermore has not established a concentration of a matrix ion species in the sample steam such that one could make a comparison to see if it were lower at the outlet. Applicant must positively claim the sample stream with a matrix ion species in the body of the claim.

Further the term "said parallel streams" lacks antecedent basis in the claim. The term "said carrier liquid stream" also does not have antecedent basis in the claims.

Claim 2 recites a detector for said one analyte ion species. There is no antecedent basis for such a term as the preamble of claim 1 recites at least one analyte ion species.

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In claims 11 and 27, Applicant states the said parallel streams are substantially planar. What does this mean? If the streams are parallel, how are they substantially planar? The streams are parallel therefore they are planar to each other, not substantially planar to each other. It is unclear how this claim is further limiting.

Claim 16 recites the term "said treating step". There is no antecedent basis for such a term.

Claims 23 and 24 respectively recite that the liquid interface is disposed substantially horizontally and substantially vertically. Without further structural limitations to the apparatus which would require such an orientation, the device may be viewed in a different orientation so as to meet the limitations of the interface being horizontally or vertically disposed. This is further because the horizontal and vertical disposition being claimed is not relative to any certain aspect so as to give a particular structural orientation.

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# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-9, 11-21, and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager (5,971,158).

Yager discloses an absorption-enhanced differential extraction device for use in affinity chromatography. Yager discloses a device and method for extracting desired particle from a sample stream containing the desired particles. Yager discloses that the device has a sample stream inlet, an extraction stream inlet, and an extraction channel (treatment channel) in fluid communication with the sample stream inlet and extraction stream inlet. Yager discloses that the extraction channel is for receiving a sample stream (such as those listed in lines 1-17, col. 8) in adjacent laminar flow with an extraction stream (comprised of an organic solvent, see lines 17-29, col. 7), wherein the extraction channel is provided with a sequestering material (matrix ion species capture material) to capture desired particles (particles defined to include ions, see lines 19-26, col. 6). Yager further discloses that a bi-product stream outlet in fluid communication with the extraction channel receives a by-product stream comprising at least a portion of the sample stream from which desired particles have been extracted (concentration lower at the outlet than at the inlet). A product outlet in fluid communication with the extraction channel receives a product, which has the sequestering material and at least

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a portion of the desired particles (abstract). Yager discloses that the sequestering material can be present in the extraction steam prior to the extraction stream's being introduced into the extraction channel, or the sequestering material can be added to the extraction stream by suspending or dissolving the sequestering material in a liquid which is introduced into the extraction stream (lines 40-46, col. 4). Yager also discloses that the sequestering material provides for increased diffusion of the desired particles (lines 47-52, col. 5). Yager also discloses that the sample and extraction streams are kept in contact in the extraction channel for a period of time sufficient to allow at least an analyzable quantity, and even small amounts of analytes present may be detected by spectroscopic and other means (line 53, col. 9 – line 5, col. 10). Yager further discloses that the invention may be utilized as a sample pretreatment system for an analytical system including sensing means for detecting desired particles in the product and byproduct streams (Examiner asserts that at least a portion of the sample steam inherently flows through). Yager discloses detection means include optical means such as spectroscopic equipment, and means for detecting fluorescence, chemical indicators, and also any magnetic resonance equipment or other means known to detect the presence of analyte particles such as ions (lines 36-57, col. 11). Yager further discloses various embodiments of extraction devices in columns 13-15.

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# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocklin (4,751,189) in view of Yager.

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Rocklin discloses a method of ion chromatography. Rocklin discloses that the system is useful for determining a large number of ionic species, such as anions and cations. Rocklin discloses that a suitable sample includes surface waters, chemical wastes, body fluids, and beverages such as fruits and wines and drinking water. Rocklin discloses that the term ionic species includes species in ionic form and components of molecules, which are ionizable under the conditions of the system (lines 53-62, col. 2). Rocklin shows in figure 1 an eluent reservoir 14 and sample 13 injected to a chromatographic separation means, such as a chromatographic column 10 which is packed with a separation medium, such as an ion-exchange resin. Rocklin discloses that arranged in series with the column 10 is a suppressor means 11 serving to suppress the conductivity of the eluent from column 10 but not the conductivity of the separated ions (lines 13-34, col. 3, fig. 1). The effluent from suppressor means 11 is directed to a detector in the form of a conductivity cell 12 for detecting all of the resolved ionic species (lines 35-54, col. 3). Rocklin discloses that in one embodiment of the suppressor device 17, effluent from the chromatographic column is directed through the effluent flow channel 26 (treatment channel) bounded on both sides by ion-exchange membranes 27, and the ion-exchange membranes are preferably permeable to ions of the same charge as the exchangeable ions of the membrane and resists permeation of ions of opposite charge. Rocklin further discloses that the membranes are simultaneously contacted on their outersides with the regenerate flowing in the opposite direction through the regenerate flow channels 28. Ions extracted from the effluent (sample stream) at the active ion-exchange sites of the membranes are diffused

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through the membranes and are exchanged with ions of the regenerate (carrier stream), and thus diffused ultimately into the regenerate (lines 8-44, col. 4). Rocklin discloses that a suitable regenerate solution is dilute sulphuric acid (lines 28-37, col. 5).

Rocklin does not disclose a matrix ion species capture material included in the carrier stream.

Yager has been discussed above.

It would have been obvious to modify Rocklin to include a sequestering material in the carrier stream such as taught by Yager in order to provide a means for increasing diffusion of the desired particles while no longer requiring the added elements of the ion exchange membranes in the flow channels.

Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager in view of Kais.

Yager has been discussed above.

Yager discloses the use of various solvents for the carrier liquid. Yager also discloses various sample streams for use within the device that are immiscible with the various organic solvents disclosed. Yager does not specifically disclose any specific pairs of solvent and sample stream which are immiscible with each other.

Kais discloses a column chromatography technique. Kais discloses that the dynamic chromatography can be utilized also in liquid ion exchangers, such as in liquidliquid extraction systems. Kais discloses that liquid-liquid extraction operates in a manner by interchange of ions at the interface between an aqueous solution and an

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immiscible solvent with negligible distribution of the extractant to the aqueous phase (lines 3-10, col. 8).

It would have been obvious for Yager to choose a given solvent and a sample stream that is immiscible with the given solvent such as taught by Kais in order to provide a liquid-liquid extraction system for interchange of ions in which there is negligible distribution of the extractant to the aqueous phase.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT